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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,055	08/29/2001	Robert Powers	GI-5452 C1	8112

25291 7590 03/24/2004

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EXAMINER	
MAHATAN, CHANNING	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,055	POWERS ET AL.	
	Examiner	Art Unit	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1-9,17,25,30 and 38-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16,18-24,26-29 and 31-37* is/are rejected.

7)☒ Claim(s) *10-14, 16, 18-21, 23, 24, 26-29 and 31-37* is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1 Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election without traverse of Group II (claims 10-16, 18, 19-24, 26-28, 29, and 31-37; drawn to a method for identifying a modulator of RGS activity, binding or RGS-Gα complex activity) is acknowledged.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 10-16, 18, 19-24, 26-28, 29, and 31-37.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

SCOPE OF ENABLEMENT

Claims 10-16, 18, 19-24, 26-28, 29, and 31-37 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the three-dimensional coordinates of "regulators of G-protein signaling-4" (RGS4; listed in Table 2), does not reasonably provide enablement for all "regulators of G-protein signaling" three-dimensional coordinates. In order to identify, select, and design by studying the interaction of a species (i.e. compound) with the three-dimensional structure of RGS one skilled in the art would require the three dimensional structure coordinates of all "regulators of G-protein signaling". Applicants have failed to provide guidance to obtain the atomic coordinates of all "regulators of G-protein signaling". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16, 18, 19-24, 26-28, 29, and 31-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 10 and all claims dependent therefrom recite the language "a portion thereof" which is vague and indefinite. It is unclear the portion encompassed by the stated language. For example, such language encompasses a single three-dimensional structure (i.e. atomic coordinate) where it is unclear that a single three-dimensional structure is indicative of RGS4

protein and/or the method claimed to use said "portion thereof" to "identify, select or design a chemical or biochemical species which is a modulator". Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 10-12, 14, 18, 19, 21, 24 and all claims dependent therefrom recite the limitation "interaction"/"predicted by its interaction"/"predicted interaction"/"interact" which is vague and indefinite. It is unclear the interactions Applicants regard said language to encompass. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 20, 23, 26, and all claims dependent therefrom recite the phrase "reversible or nonreversible bond" which is vague and indefinite. It is unclear what Applicants regard as a "reversible or nonreversible bond". Applicants can resolve this issue by particularly pointing out the criterias that establishes a bond is "reversible" as opposed to "nonreversible". Further, it is unclear what limitation(s) Applicants' regard within the context of designing step, wherein absent a selection of either a "reversible or nonreversible bond". Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 33-37 recite the limitation "capable of binding to" which is vague and indefinite. It is unclear what Applicants' intend such language to encompass, wherein absent are criteria(s)/parameter(s) that is considered to identify a chemical or biochemical species as "capable of binding to". Clarification of the metes and bounds, via clearer claim language, is requested.

MISSING ESSENTIAL STEPS

Claims 28, 29, and 31-37 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

See MPEP § 2172.01. Independent claim 28 (which claims 29, 31-37 depend from) recites only "A method for identifying a potential modulator of RGS activity, RGS binding or RGS-Gα complex activity by rational drug design comprising the steps:". However, no further steps are recited and it is unclear the steps Applicants desire the claim to encompass. Clarification of the instant claim language is requested.

LACK OF ANTECEDENT BASIS

Claims 29 and 31-37 refer to steps and limitations in claim 28 which lacks proper antecedent basis. None of these limitations can be found within claim 28 (Refer to above 'Missing Essential Steps').

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 10-16, 18, 19-24, 26-28, 29, and 31-37 are rejected under 35 U.S.C. § 102(a) as being anticipated by Alba et al.

Alba et al. describes the comparison interactions between the solution structure of Gα interacting protein (GAIP) and the crystal structure of regulator of G-protein signaling (RGS4), wherein GAIP is indicated a regulator of G-protein signaling (Abstract; pages 931-935). Alba et al. indicates comparison of GAIP and RGS4 reveals the way RGS proteins interact with Gα and possible differences in their efficiency as Gα regulators (page 931, right column, lines 12-15).

Additionally, the authors indicate Figures 3-8 have been generated using Koradi et al. (Refer to below 35 U.S.C. § 103 Rejection). Thus, Alba et al. anticipates the claimed invention.

Claims Rejected Under 35 U.S.C. § 103

Claims 10-16, 18, 19-24, 26-28, 29, and 31-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Koradi et al.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-16, 18, 19-24, 26-28, 29, and 31-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Koradi et al.

The following excerpt is from M.P.E.P. § 2106 Section VI "DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. § 102 AND 103" (particular emphasis on bolded areas) and is applied to the below 35 U.S.C. § 103 rejection, wherein the "the three-dimensional solution structure of an RGS4 protein or a portion thereof"; and 2) "NMR structure coordinates" are considered "non-functional descriptive" material (i.e. mere arrangement of data; failing to satisfy the practical application requirement). Further, examples are provided for in the M.P.E.P. regarding situations of nonfunctional descriptive material.

> As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. **If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102.** Once distinctions are identified between the claimed invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law

> governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See Dann v. Johnston, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976); In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).
>
> If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). **Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).** Common situations involving nonfunctional descriptive material are:
>
> - a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
>
> - a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
>
> - a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.
>
> Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

All limitations concerning the type of data are given no patentable weight as they are considered to be non-functional descriptive material. As such, the claim limitations are considered to be limited to a memory storing any data, a processor in communication with memory, and capable of generating a three-dimensional model.

Koradi et al. describes a molecular graphics program for the display, analysis, and manipulation of three-dimensional structures of biological molecules, with special emphasis on nuclear magnetic resonance solution structures of proteins and nucleic acids (Abstract; and page 51). The program allows for: 1) evaluation and comparison of molecular structures; 2) different

conformations and/or different structures can be superimposed and quantitatively compared (i.e. root mean square distances, interatomic contacts, dihedral angles, hydrogen bonds, solvent-accessible surfaces); and 3) generation of high quality pictures. Thus, Koradi et al. makes it obvious to study any three-dimensional structure with any other three-dimensional structure to determine types of interactions.

OBJECTION TO CLAIMS

Claims 10-14, 16, 18-21, 23, 24, 26-29, 31-37 are objected to because of the following informalities:

Claims 10-14, 16, 18-21, 23, 24, 26, 28, 29, and 31-37 recite the abbreviation "RGS" which is improper. Applicants' are requested to replace "RGS" with "regulator of G-protein signaling" as denoted in the specification (page 3, line 5).

Claim 27 is objected to because of a typographical error. It appears the instant claim language "...modulator activity is assesses..." should be replaced with "...modulator activity is assessed...".

Appropriate Correction Is Requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: March 17, 2004

Examiner Initials: CSM

MARIANNE P. ALLEN
PRIMARY EXAMINER
3/15/04

AU 1631